

<b>TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT</b> <b>(Under 37 CFR 1.97(b) or 1.97(c))</b> <small>NOV 14 2005</small>					Docket No. <b>18688</b>
<small>On Re Application Of:</small> <b>Kathryn E. Lawlor et al.</b>					
Application No. <b>10/525,363</b>	Filing Date <b>February 23, 2005</b>	Examiner <b>Unassigned</b>	Customer No. <b>23389</b>	Group Art Unit <b>Unassigned</b>	Confirmation No. <b>5197</b>
<b>Title: A METHOD OF TREATMENT AND PROPHYLAXIS</b>					
Address to: <b>Commissioner for Patents</b> <b>P.O. Box 1450</b> <b>Alexandria, VA 22313-1450</b>					
<b>37 CFR 1.97(b)</b>					
<p>1. <input checked="" type="checkbox"/> The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.</p>					
<b>37 CFR 1.97(c)</b>					
<p>2. <input type="checkbox"/> The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:</p>					
<p style="margin-left: 20px;"><input type="checkbox"/> the statement specified in 37 CFR 1.97(e);</p>					
<b>OR</b>					
<p style="margin-left: 20px;"><input type="checkbox"/> the fee set forth in 37 CFR 1.17(p).</p>					

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**  
**NOV 14 2005 (Under 37 CFR 1.97(b) or 1.97(c))**

Docket No.  
18688

In Re Application of  
*KATHRYN E. LAWLOR ET AL.*

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/525,363	February 23, 2005	Unassigned	23389	Unassigned	5197

Title: A METHOD OF TREATMENT AND PROPHYLAXIS

**Payment of Fee**

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

- A check in the amount of \_\_\_\_\_ is attached.
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Edward W. Grolz

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Signature

Dated: November 10, 2005

Edward W. Grolz  
Registration No. 33,705

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cc: EWG:ab



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

<b>Applicants:</b>	Kathryn E. Lawlor et al.	<b>Examiner:</b>	Unassigned
<b>Serial No.:</b>	10/525,363	<b>Art Unit:</b>	Unassigned
<b>Filed:</b>	February 23, 2005	<b>Docket:</b>	18688
<b>For:</b>	A METHOD OF TREATMENT AND PROPHYLAXIS	<b>Dated:</b>	November 10, 2005
		<b>Confirmation No:</b>	5197

Mail Stop Amendment  
 Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with 37 C.F.R. §§ 1.97 and 1.98, it is requested that the following references, which are also listed on the attached Form PTO-1449, be made of record in the above-identified case.

1. United States Patent No. 5,420,109 dated May 30, 1995, issued to Suto et al.;
- 

**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on November 10, 2005.

Dated: November 10, 2005

Edward W. Grolz

2. United States Patent No. 5,639,455, dated June 17, 1997, issued to Shimomura et al.;
3. United States Patent Application Publication No. 2002/0141994 dated October 3, 2002, issued to Devalaraja et al.;
4. International Patent Publication No. 95/21864, dated August 17, 1995;
5. International Patent Publication No. 95/21867, dated August 17, 1995;
6. International Patent Publication No. 02/07676, dated January 31, 2002;
7. Bernard, L.A. et al., "Pimecrolimus 1% Cream (Elidel<sup>®</sup>) For Atopic Dermatitis," *Skin Therapy Letter.* 7(4): 1-3, (2002);
8. Campbell, Ian et al., "The Colony-Stimulating Factors and Collagen-Induced Arthritis: Exacerbation of Disease by M-CSF and G-CSF and Requirement for Endogenous M-CSF," *J. of Luekocyte Bio.* 68: 144-150, (2000);
9. Ghivizzani, Steve C. et al., "Gene Therapy Approaches for Treating Rheumatoid Arthritis," *Clin. Orthopaedics and Related Research.* 379S: S288-S299, (2000);
10. Hermans, Mirjam et al., "Sustained Receptor Activation and Hyperproliferation in Response to Granulocyte Colony-Stimulating Factor (G-CSF in Mice with a Severe Congenital Neutropenia/Acute Myeloid Leukemia-derived Mutation in the G-CSF Receptor Gene," *J. Exp. Med.* 189(4): 683-691 (1999);
11. Caporali, Roberto et al., "Cyclophosphamide Plus Granulocyte Colony Stimulating Factor (G-CSF) is More Effective than G-CSF Alone in Mobilizing Hemopoietic Progenitor Cells in Severe, Refractory Rheumatoid Arthritis," *Haematologica.* 86(1): 106-107 (2001);
12. Kawamura, Hiroki et al., "Expansion of Extrathymic T Cells as Well as Granulocytes in the Liver and Other Organs of Granulocyte-Colony Stimulating Factor Transgenic Mice: Why They Lost the Ability of Hybrid Resistance," *J. of Immunology.* 162: 5957-5964, (1999);
13. Roessler, Blake J. et al., "Inhibition of Interleukin-1-Induced Effects in Synoviocytes Transduced with the Human IL-1 Receptor Antagonist cDNA Using an Adenoviral Vector," *Human Gene Therapy.* 6: 307-316, (1995); and
14. Saggio, I. et al., "Adenovirus-Mediated Gene Transfer of a Human IL-6 Antagonist," *Gene Therapy.* 4: 839-845, (1997).

Reference numbers 1-3, 7-10 and 12-14 were cited in an International Search Report, dated November 20, 2003, a copy of the search report was filed on February 23, 2005, therefore a copy is not provided. Applicants are submitting copies of reference numbers 7-10 and 12-14.

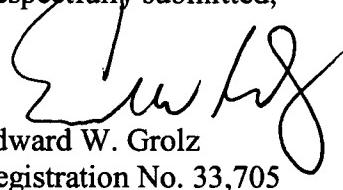
In accordance with the waiver of 37 C.F.R. § 1.98 (a)(2)(i) in effect as of June 30, 2003, applicants are not required to submit copies of the U.S. Patent references (reference numbers 1-3).

Reference numbers 4-6 and 11 were cited in a Supplementary Partial European Search Report dated July 28, 2005. Applicants are submitting a copy of the search report together with a copy of the references. The relevance of these references has been described in the Search Report.

Consideration of this Information Disclosure Statement is respectfully requested, since the art provided may be material to the examination of the present application as defined under 37 C.F.R. §1.56.

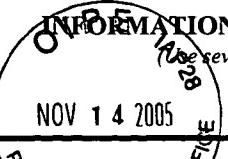
Inasmuch as this Information Disclosure Statement is being submitted in accordance with the schedule set out in 37 C.F.R. § 1.97(b), no statement or fee is required.

Respectfully submitted,



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Enclosure: Form PTO 1449

<p style="text-align: center;"><b>INFORMATION DISCLOSURE CITATION</b> <i>(Use several sheets if necessary)</i></p> <p style="text-align: center;">NOV 14 2005</p> 				Docket Number (Optional) <b>18688</b>		Application Number <b>10/525,363</b>		
				Applicant(s) <b>Kathryn E. Lawlor et al.</b>				
				Filing Date <b>February 23, 2005</b>		Group Art Unit <b>Unassigned</b>		
				<b>U.S. PATENT DOCUMENTS</b>				
*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
/CMW/		<b>5,420,109</b>	<b>5/30/1995</b>	<b>Suto et al.</b>	-----	-----		
/CMW/		<b>5,639,455</b>	<b>6/17/1997</b>	<b>Shimomura et al.</b>	-----	-----		
<b>U.S. PATENT APPLICATION PUBLICATIONS</b>								
*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
/CMW/		<b>2002/0141994</b>	<b>10/3/2002</b>	<b>Devalaraja et al.</b>	-----	-----		
<b>FOREIGN PATENT DOCUMENTS</b>								
	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO
/CMW/		<b>95/21864</b>	<b>8/17/1995</b>	<b>WO</b>	-----	-----		
/CMW/		<b>95/21867</b>	<b>8/17/1995</b>	<b>WO</b>	-----	-----		
/CMW/		<b>02/07676</b>	<b>1/31/2002</b>	<b>WO</b>	-----	-----		
<b>OTHER DOCUMENTS</b> <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>								
/CMW/		<b>Bernard, L.A. et al., "Pimecrolimus 1% Cream (Elidel) For Atopic Dermatitis," Skin Therapy Letter. 7(4): 1-3, (2002);</b>						
/CMW/		<b>Campbell, Ian et al. "The Colony-Stimulating Factors and Collagen-Induced Arthritis: Exacerbation of Disease by M-CSF and G-CSF and Requirement for Endogenous M-CSF," J. of Leukocyte Bio. 68: 144-150, (2000);</b>						
EXAMINER <i>/Cherie M. Woodward/</i>				DATE CONSIDERED <b>01/02/2008</b>				
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.								

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	<b>Ghivizzani, Steve C. et al., "Gene Therapy Approaches for Treating Rheumatoid Arthritis," <i>Clin. Orthopaedics and Related Research.</i> 379S: S288-S299, (2000);</b>		
	<b>Hermans, Mirjam H.A. et al., "Sustained Receptor Activation and Hyperproliferation in Response to Granulocyte Colony-Stimulating Factor (G-CSF) in Mice With a Severe Congenital Neutropenia/Acute Myeloid Leukemia-Derived Mutation in the G-CSF Receptor Gene," <i>J. Exp. Med.</i> 189(4); 683-691 (1999);</b>		
	<b>Caporali, Roberto et al., "Cyclophosphamide Plus Granulocyte Colony Stimulating Factor (G-CSF) is More Effective Than G-CSF Alone in Mobilizing Hemopoietic Progenitor Cells in Severe, Refractory Rheumatoid Arthritis," <i>Haematologica.</i> 86(1): 106-107 (2001);</b>		
	<b>Kawamura, Hiroki et al., "Expansion of Extrathymic T Cells as Well as Granulocytes in the Liver and Other Organs of Granulocyte-Colony Stimulating Factor Transgenic Mice: Why They Lost the Ability of Hybrid Resistance," <i>J. of Immunology.</i> 162: 5957-5964, (1999);</b>		
	<b>Roessler, Blake J. et al., "Inhibition of Interleukin-1-Induced Effects in Synoviocytes Transduced with the Human IL-1 Receptor Antagonist cDNA Using an Adenoviral Vector," <i>Human Gene Therapy.</i> 6: 307-317, (1995); and</b>		
<b>↓</b> <b>/CMW/</b>	<b>Saggio, L. et al., "Adenovirus-Mediated Gene Transfer of a Human IL-6 Antagonist," <i>Gene Therapy.</i> 4: 839-845, (1997).</b>		
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